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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,668

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Branson W. Ritchie

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,668

Applicant(s)

RITCHIE ET AL.

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statement dated 1/13/06.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7,9-19,23,24,28-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,6,7,9,11-34,43-47,51-60,65-74 and 76-78 of copending Application No. 10/739,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of applying a cleansing composition to the skin comprising chelating agents and antimicrobial agents working synergistically. The formulations both comprise detergents, carriers and pH buffers that support and preserve the stability of the formulation. The difference between the claims is the intended methods of use. The instant claims are intended for basic skin cleansing while the copending claims are drawn to a wound cleansing. However these

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limitations are merely a future intended use and bare no patentable weight. Further the methods of each method are identical by simply applying the composition to the skin. For these reasons the claims act as obviating art over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 24-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,5-15,18-22 and 56-62 of copending Application No. 09/955,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because both steps of claims are drawn methods of using cleansing composition comprising a synergistic combination of antimicrobial compounds and chelating agents. The claims differ in their intended use, however these uses do not impart patentability on the claims. For these reasons the claims act as obviating art over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6,9,11,17,19,23,24,26-31,37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulder (USPN 5,565,189 hereafter '189). The claims are drawn to a

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cleansing formulation comprising chelating agents, pH buffers, a detergent and other carriers.

The claims are also drawn to a method of using the composition to cleans the skin.

6. The '189 patent teaches a method of cleaning the skin comprising the application of a cleansing composition comprising a carrier, water and aloe vera gel, a pH buffer such as sodium borate, chelators such as EDTA, vitamin E surfactants such as cocamphoacetate and biocides such as hydroxyquinoline (example 1). The method further debriding the wound site, rinsing the composition after it is applied (col. 4, lin. 45-55). The pH of the composition is between pH 6.5-6.8 (col. 4, lin. 3-10). The formulation includes sensitizers that relieve pain (example 1). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
11. Claims 1,7,8,12-16,18,25,32-36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder (USPN 5,565,189 hereafter '189) in view of both Steel et al (USPN 6,224,853 hereafter '853) and Huber et al (USPN 3,758,682 hereafter '682). The claims are drawn to a cleansing composition comprising detergents such as cocamidopropyl betaine and a pH buffer such as Tris (hydroxymethyl) aminomethane base. The claims also recite a method of using the cleansing composition along with a kit comprising instructions.
12. As discussed above the '189 patent discloses a cleansing composition comprising detergents (surfactants) and alkaline pH buffers (sodium borate) but does not disclose the specific compounds of the instant claims. However these compounds are well known and their inclusion is within the level of skill in the art as shown by the '853 and the '682 patents.
13. The '853 patent discloses an aqueous formulation comprising lanolin and further co-surfactants such as cocamidopropyl betaine and lecithin where the surfactant is present in a concentration from 1-25% (col. 4, lin. 18-39, col. 5, lin. 20-45; col. 6, lin. 40-50). It would have

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been obvious to include these surfactants and components into the formulation of the '189 in order to reduce the irritation to the applied area.

14. The '682 patent discloses a formulation useful in wound healing comprising a buffer solution comprising tris(hydroxymethyl) amino methane (col. 13, lin. 25-30). Further the composition can be administered orally contacting the oral mucosa (col. 24, lin. 19-53). The artisan of ordinary skill would have been motivated to include these components in order to improve the stability of the wound treating formulation.

15. Regarding the specific ranges and concentrations of the specific components, it is the position of the Examiner that such limitations do not patentability to the claims. The '189 patent though silent to the molar ratios of the buffers, chelators and active agents, the reference discloses from 0.08-0.12% of a chelating agent and up to 1% buffers in the formulation. The vitamin E concentrations are equally low. It is the position of the Examiner that the general conditions of the claims have been met. It is the position of the Examiner that the concentrations and ratios are well within the level of skill in the art to optimize in order to arrive at the current invention and to provide a stable formulation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

16. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

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patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

17. Regarding the specific application points of the cleansing compositions it is the position of the Examiner that the specific are of application does not impart patentability to the claims in view of the prior art. The '189 and '853 patents disclose that the cleansing formulation is applied to the skin and hair to all parts of the body (col. 6, lin. 35-50). It is the position of the Examiner that it would be obvious to an artisan of ordinary skill to apply the cleansing to any portion of the body.

18. With these things in mind it would have been obvious to combine the detergents and buffers of the '853 and '682 patents into the cleansing formulation of the '189 patent in order to improve the stability of the cleansing formulation. It would have been obvious to combine these compounds with an expected result of a stable cleansing composition and improve method of cleansing and disinfecting the skin at a wound site.

19. Claims 1,4,10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulder et al (USPN 5,565,189 hereafter '189) in view of Robertson et al (USPN 4,939,135 hereafter '135). The claims are drawn to a method of wound management comprising applying a composition comprising a chelator and other antimicrobial agents.

20. As discussed above the '189 patent discloses a method of wound management comprising the application of a composition comprising antimicrobial agents and chelating agents such as EDTA. The reference is silent to the molar concentrations of the chelators and buffers, however the concentrations of the chelators are approximately from 0.08-0.12% of the

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total formulation and the buffers represent up to 1% of the formulation. It is the position of the Examiner that these components would be well within the level of skill in the art to optimize in order to arrive at the current invention since the molar concentrations and IU depended on the volume of the applied formulation.

21. The '189 patent further is silent to the specific active agents of the instant claims. However the inclusion of these agents is well known in the art as seen in the '135 patent. The '135 patent discloses a wound healing formulation and method of applying the formulation to an ocular injury (abstract). The formulation comprises anti-inflammatory agents such as dexamethasone and antimicrobials such as neomycin and vancomycin (col. 4, lin. 60-65; col. 9, lin. 60-68). The active agents are in a concentration from 0.5-1.0% of the total formulation (col. 8, lin. 1-5). The formulation further comprises chelators and sorbic acid (col. 10, lin. 60-65). The artisan of ordinary skill would be motivated to combine the components of the '189 patent with those of the '135 patent since they both solve the same problem of wound management with cleansing compositions.

22. With these things in mind it would have been obvious to combine the teachings in order to improve the efficiency of the wound treatment of the '135 patent. It would have been obvious to combine the teachings with an expected result of an improved method of treating ocular wounds.

23. Claims 1,21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder (USPN 5,565,189 hereafter '189) in view of Gehlsen (USPN

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6,270,781 hereafter '781). The claims are drawn to a topical formulation comprising pH stabilizers, detergents, antimicrobial agents, colorants and perfumes.

24. As discussed above the '189 patent discloses a skin cleansing formulation comprising pH stabilizers, detergents, antimicrobial agents and other components with inherent fragrances such as aloe vera and lanolin (examples). The reference however is silent to additional perfumes and colorants. The inclusion of these components is well within the level of skill in the art as seen in the '781 patent.

25. The '781 patent discloses a topical skin composition comprising detergents, antimicrobial agents, perfumes and pigments (col. 8, lin. 6-15; col. 8, lin. 57-65; col. 9, lin. 28-32). The artisan of ordinary skill would have been motivated to include the pigments and perfumes of the '781 with the formulation of the '189 since they comprise similar components in the same field of endeavor.

26. One of ordinary skill in the art would have been motivated to combine the components of the '781 patent in to the formulation of the '189 patent in order to improve the aesthetic properties of the cleansing formulation. It would have been obvious to combine these components with an expected result of an aesthetically pleasing fragrant skin cleansing composition.

27. Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder (USPN 5,565,189 hereafter '189) in view of Horn (USPN 5,848,700 hereafter '700). The claims are drawn to a kit comprising a skin cleanser and instructions to use the cleanser.

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28. As discussed above the '189 patent discloses a skin cleansing formulation comprising chelators, carriers, pH buffers, a detergent and an antimicrobial agent. The reference discloses instructions of the use and application of the skin cleansing composition. The reference discloses method of applying the cleansing to the skin by is silent to a specific kit. The inclusion of a kit is well known in the art and shown in the '700 patent.

29. The '700 patent discloses a kit comprising instructions for various applications methods inclusion cleansing the skin of burns, cuts, wounds and fractures (claims). It would have been obvious to include the skin cleanser of the '189 with the instruction of the '700 since they both endeavor to treat wounds.

30. One of ordinary skill in the art would have been combine the instructions of the '700 patent with the cleanser of the '189 patent in order to form a kit to ensure proper and safe use of the cleansing formulation. One of ordinary skill in the art would have been motivated to make the combination with an expected result of a kit comprising a skin cleansing formulation and instructions for proper and safe use that would be accessible to those of ordinary skill it the art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER